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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,963	03/31/2000	Thomas S. Kupper	B0801/777170 (JRV)	2087

7590 06/08/2004

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/540,963	KUPPER ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,12-14,18-21,25,28,30,36,37 and 48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,5,7,12,13,28,30,37 and 48* is/are allowed.

6)☒ Claim(s) *14,18-21,25 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/04 has been entered. Claims 6 and 29 have been canceled. Claims 1, 5, 7, 12-14, 18-21, 25, 28, 30, 36-37, and 48 are currently pending and under examination in the instant application. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 112

The rejection of pending claims 1, 5, 7, 12-14, 18-21, 25, 28, 30, 36-37, and 48 under 35 U.S.C. 112, first paragraph rejected under 35 U.S.C. 112, first paragraph, is withdrawn over claims 1, 5, 7, 12-13, 28, 30, 36-37, and 48 and maintained over claims 14, 18-21, and 25. Applicant's arguments have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reason of record as discussed in detail below.

The applicant argues that the amendments to the claims have overcome the examiner's concerns regarding the lack of enablement for "targeting dendritic cells to lymphoid or non-

lymphoid tissues which express a selectin ligand by transfecting the dendritic cells with an expression vector encoding any selectin other than an E/L-selectin chimera", and for "generating therapeutic or antigen-specific immune responses *in vivo* wherein the dendritic cells have not been pulsed with or transfected to express antigen". Applicant's arguments have been found persuasive regarding claims 1, 5, 7, 12-13, 28, 30, 36-37, and 48, see above. However, applicant's arguments are not persuasive regarding the subject matter of claims 14, 18-21, and 25. Claims 14, 18-21, and 25 are drawn to targeting dendritic cells to secondary lymphoid or non-lymphoid tissue which expresses a selectin by administering platelet modified dendritic cells (claims 14 and 18-20), or by administering activated platelets or membrane microparticles thereof prior to or concurrently with the administration of dendritic cells. The office actions mailed to the applicants on 10/4/01 and 2/11/03 clearly stated that the specification does not reasonably provide enablement for methods of delivering recombinant dendritic cells to any tissue in a mammal by transfecting said cell with any portion of an L, E, or P selectin, or for methods of delivering recombinant dendritic cells to any tissue in a mammal administering compositions comprising activated platelets and dendritic cells.

The applicant's amendments and arguments have addressed the claims drawn to recombinant dendritic cells. The amendments and arguments do not address the lack of enablement for targeting dendritic cells by administering compositions comprising activated platelets and dendritic cells. It is noted that the applicant's arguments filed on 8/13/03 after the final office action state that they are confused by this rejection because according to the applicants, the claims recite the administration of platelet modified dendritic cells not a composition comprising activated platelets and dendritic cells. However, claims 21 and 25

clearly recite providing isolated dendritic cells, providing isolated activated platelets or membrane microparticles thereof which contain P-selectin and administering the two either separately or concurrently. The specification is silent as to whether isolated activated platelets or membrane microparticles thereof are capable of modifying dendritic cells *in vivo*, particularly in the case where the platelets are administered before the dendritic cells. The specification provides no guidance as to whether activated platelet modification of dendritic cells is a natural phenomenon, or that injected activated platelets and dendritic cells would be capable of targeting and binding to each other in an *in vivo* environment, particularly in circulating blood. The working examples, as noted in previous office actions and below, clearly teach the binding of activated platelets to dendritic cells *in vitro* in tissue culture. Further, regarding claims 14 and 18-21, the previous office actions stated that while the specification does provide a working example demonstrating that incubation of dendritic cells with whole live thrombin activated platelets *in vitro* results in the binding of the platelets to the dendritic cells, and that the administration of dendritic cells bound to activated platelets to a host results in rolling of the dendritic cells in high endothelial venules (HEV) *in vivo*. The specification is silent in regards to methods of preparing membrane microparticles comprising P-selectin from the activated platelets and further provides no guidance whatsoever as to the conditions under which said membrane microparticles could bind to dendritic cells and mediate tethering and rolling in HEV. In the absence of any such guidance, it would have required undue experimentation to practice the scope of the instant invention as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 36 is rejected under 35 U.S.C. 102(a) as being anticipated by Bondanza et al. (1998) J. Leuk. Biol., Suppl. 2, page70, abstract F17, as evidenced by . The applicant claims a composition comprising isolated dendritic cells and isolated activated platelets or membrane microparticles thereof which contain P selectin.

Bondanza et al. teaches a composition comprising isolated thrombin activated platelets and isolated dendritic cells (Bondanza et al., abstract). Thrombin activated platelets inherently contain P-selectin as evidenced by Whiss et al. (1998) Cell Adh. Commun., Vol. 6(4), 289-300. Thus, by teaching all the elements of the claim as written, Bondanza et al. anticipates the instant invention as claimed.

Claims 1, 5, 7, 12-13, 28, 30, 37, and 48 are free of the prior art of record and considered allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's

supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER